

GUIDE TO THE BNL QUALITY ASSURANCE PROGRAM

OVERVIEW

BNL, as one of the leading multi-program research laboratories, has established a reputation for quality research. This position has come through innovative approaches to research, and the proper management of the research effort and associated support activities. This booklet describes the Quality Principles and supporting guidelines incorporated into the Lab's work practices that contribute to the consistent achievement of planned goals. These principles and guidelines form the basis of the BNL Quality Assurance Program.

QUALITY PRINCIPLES

- Define policies and goals.
- Specify roles and responsibilities.
- Specify and communicate expectations. Identify and allocate resources to achieve them.
- Strive to improve.
- Ensure people are competent at the work they do.
- Ensure the right people have the right information at the right time.
- Seek and use relevant experience.
- Plan and control the work.
- Use the right materials, tools, and processes.
- Assess work to ensure it meets expectations.
- Identify and remedy errors and deficiencies.
- Periodically review management and work processes to improve effectiveness and efficiency.

WHAT IS QUALITY MANAGEMENT?

Quality Management is a way of doing business which continuously improves processes and support services to achieve increasing levels of user satisfaction. It includes work planning, work performance, review of results, and actions to address differences between results and established aims or requirements (Also known as Plan, Do, Check, Act). DOE has issued order 5700.6C, and rule 10

CFR 830.120 which provides Quality Assurance requirements for its facilities. By implementing these criteria, using a graded approach, work is to be performed and managed with a consistent set of processes which can be readily assessed. Quality Management should be applied to all work performed.

WHAT IS GRADED APPROACH?

Graded Approach is a concept by which the actions taken are commensurate with an item's/activity's potential to create adverse results, such as:

- Create an environmental, safety, or health hazard.
- Result in or create a monetary loss due to damage, or due to repair/rework/scrap costs.
- Reduce the availability of a facility or its equipment.
- Adversely affect the program objective or degrade data quality.
- Unfavorably impact the public's perception of the BNL/DOE mission.

The greater the adverse impact, the more extensive the actions.

Through the use of the Graded Approach, resources can be effectively utilized depending on what makes sense for your program.

WHAT IS QA CATEGORY?

A QA category is the designation of an activity, task or process.

Category A, Construction, Operation and Management of Facilities, Equipment and Infrastructure to Support Research. Any activity that is involved with constructing or modifying a facility, research apparatus, or item of equipment; and any activity involved with operating, monitoring, or maintaining a research facility. When a program, project, study or experiment is designated as Category A, the various systems, assemblies, components, and activities are further classified as either Critical (A-1), Major (A-2), Minor (A-3), or Other (A-4). Category A is used in conjunction with the Graded Approach.

Category B, Research - The actual performance of research. That is, any activity involved with a study, investigation or experiment aimed at the discovery

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or interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or reviewed theories or laws. Note: The equipment or facilities used by the researcher are covered under Category A. **Thus, most research has a Category A element.**

GUIDELINES

MANAGEMENT ACTIVITIES

- *Program* - Depts./Divs./Projs. will develop, implement, and maintain a written Quality Assurance (QA) Program. The QA Program will outline the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work and associated processes. Each Dept./Div. Designates a Quality Representative to act as a focal point, for Dept./Div. QA program.
- *Personnel Training and Qualifications* - Personnel will be trained and qualified to ensure that they are capable of performing their assigned work. Continuing training will be provided to ensure job proficiency.
- *Quality Improvement* - Depts./Divs./Projs. will establish and implement processes to detect and prevent problems and promote improvement. Items and processes that do not meet established requirements will be identified, controlled, and corrected. Causes of problems will be identified and steps will be taken to prevent avoidable recurrence. Information will be analyzed to identify items and processes needing improvement.
- *Documents and Records* - Documents will be prepared, reviewed, approved, issued, used, and revised according to established practices and procedures. Records will be specified, prepared, reviewed, approved, and maintained.

PERFORMANCE ACTIVITIES

- **Work Processes** - Work will be performed to technical standards under administrative controls defining controlled conditions, approved instructions, procedures, or other appropriate guidance. Where necessary, items will be identified and controlled to ensure their proper use. These items will be maintained to prevent their deterioration, damage, or loss. Equipment requiring calibration will be identified and calibrated per established requirements.
- **Design** - Items and processes will be designed using appropriate engineering and scientific principles and standards.
- **Procurement** - Requirements for procured items and services will be specified. Prospective suppliers will be evaluated and selected on the basis of specified criteria.
- **Inspection and Testing** - Inspection and testing of specified items and processes must be conducted using established acceptance and/or performance criteria and designated equipment.

ASSESSMENT ACTIVITIES

Assessments are performed to assure that requirements are met. Deficiencies are identified and corrected.

- **Management Assessment** - Management will periodically assess the Dept./Div./Proj. QA Program. Problems that hinder the achievement of objectives will be identified and corrected. Areas identified for improvement should also be addressed.
- **Independent Assessment** - Planned and periodic independent assessments shall be conducted to measure item/service conformance to established requirements/goals, effectiveness of management systems, and to promote improvement. The group performing these assessments shall have sufficient authority and freedom from the line organization.

QA REFERENCES

- Quality Assurance, DOE Order 5700.6C.
- DOE Standard Implementation Guide for Quality Assurance Programs for Basic & Applied Research, DOE-ER-STD-6001-92.
- 10 CFR 830.120 Quality Assurance Requirements (applicable to Nuclear Facilities)
- Implementation guide for use with 10 CFR 830.120.
- BNL Quality Assurance Manual

